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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,908	08/15/2001	Diane McGhee	20518/9 (S-8457)	9256
75	90 12/03/2002			
Mark S. Leonardo, Esq.			EXAMINER	
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Box IP	Box IP			
Boston, MA 02111			ART UNIT	PAPER NUMBER
			1615	9
			DATE MAILED: 12/03/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
	•	09/929,908	MCGHEE ET AL.			
Office Action Summary		Examiner	Art Unit			
		Rachel M. Bennett	1615			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1) Responsive	to communication(s) filed on 16 A	<u>lugust 2001</u> .				
2a) This action	is FINAL . 2b)⊠ Thi	s action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4) Claim(s) 1-45 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) ☐ Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8)⊠ Claim(s) <u>1-4</u> 5	8) Claim(s) 1-45 are subject to restriction and/or election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References 2) Notice of Draftspersor	Cited (PTO-892) o's Patent Drawing Review (PTO-948) o Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal I	/ (PTO-413) Paper No(s) Patent Application (PTO-152)			
U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)	Office Ac	tion Summary	Part of Paper No. 2			

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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28, drawn to a flexible coating, classified in class 424, subclass 422.
 - II. Claims 29-43, drawn to a method for producing a coating, classified in class 424, subclass 400.
 - III. Claims 44, drawn to a method for controlling the release rate, classified in class 424, subclass 424.
 - IV. Claim 45, drawn to a method of producing a coating, classified in class 424, subclass 400.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. The method of Group II requires an emulsifier, whereas the method of Group IV does not require the presence of an emulsifier.
- 3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product. It is also well known in the art to use methyl acrylic polymers to control the rate of release of a medicinal additive.

- 4 Invention III and II are independent and distinct in that there are two different methods which are not connected by operation or design.
- 5. Invention III and IV are independent and distinct in that there are two different methods which are not connected by operation or design.
- 6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 7. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.
- 8. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species in Group I:

- a) pharmacological compounds in claims 9, 23
- b) pharmacological compounds in claims 10, 24
- c) pharmacological compounds in claims 11, 25

Species in Group II:

- a) pharmacological compounds in claim 41
- b) pharmacological compounds in claim 42

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c) pharmacological compounds in claim 43

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 15 and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett November 21, 2002

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